

# Notice of Allowability

Application No.

10/019,052

Examiner

Mark L. Shibuya, Ph.D.

Applicant(s)

NEW ET AL.

Art Unit

1639

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendments to the claims, specification, declarations and RCE, all filed 9/13/2007.
2. ☒ The allowed claim(s) is/are 2-10 and 32-34.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All b) ☐ Some\* c) ☐ None of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

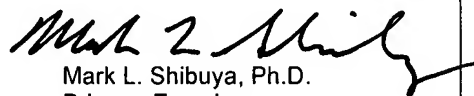
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 11/20/07.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
Mark L. Shibuya, Ph.D.  
Primary Examiner  
Art Unit: 1639

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Martha Cassidy on 11/20/2007.

The application has been amended as follows:

In the claims:

Claims 23-31 are canceled.

In claim 2, the language -- the group consisting of-- is inserted after the term "from" in line 2.

In claim 32, the term -micelles-- replaces the term "micelle" in line 2.

### **REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance:

The Declarations ("Declaration I" and "Declaration II" by Inventor Roger Randal Charles New) under 37 CFR 1.132 filed 9/13/2007 are sufficient to overcome the

objection for new matter to the amendment to the specification and the rejections of claims 1-12 and 32 based upon the publications of Crabtree et al., WO 95/02684 A1; Capon et al., WO 96/23881 A1; Ueda et al., US 2003/0095962 A1; and Onyuksel et al., US 6,217,886 B1.

In particular regard to overcoming the claim rejections of record, Declaration II, at p. 2, para 8, states that the head groups are preferably oligopeptides wherein the length of each peptide chain "would not normally exceed ten amino acids, preferably six or less." Declaration II, at p. 3, para 9-11, notes that the prior art of Crabtree, Capon and Ueda, teach receptor domain of 50, 50-15000 and 70 amino acids, respectively.

Importantly, Declaration II states:

The peptides attached to the surface of the micelles described in Onyuksel are also larger than described in the present invention, and because of this size, structure, and method of adherence to micelles, do not have sufficient flexibility or freedom of movement to allow adjacent peptides to come together in all possible configurations to enable formation of new epitopes.

Declaration II, at p. 5.

It is respectfully noted that independent base claim 32, in lines 19-20, recites the limitation that "a distinct non-covalent association of the head group molecules forms an epitope".

In view of the evidence provided in Declaration II, the aforementioned limitation of claim 32 is found to impose structural limitations upon the head group molecules of the micelles such that these molecules are able to form an epitope. Thus the head group molecules must be small enough to form an epitope, as evidenced by Declaration II. Furthermore, the epitope of the claimed invention is not pre-existing, (such as the

Art Unit: 1639

domains taught by Crabtree, Capon and Ueda), but formed by the head group molecules in the context of the micelle, as claimed. As previously noted, Declaration II explicitly provides that examples of suitable head group molecules would be oligopeptides of less than ten amino acids.

Therefore, it is respectfully considered by the examiner, in view of the evidence furnished in Declaration II, that the limitations of claim 32 impose structural limitations upon the micelles that distinguish the claimed invention from the aforementioned references of Crabtree, Capon, Ueda and Onyuksel.

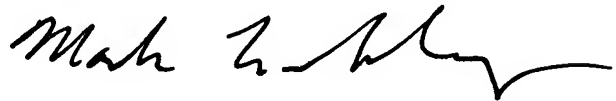
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya, whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Mark L. Shibuya', with a stylized flourish at the end.

Mark L. Shibuya, Ph.D.  
Primary Examiner  
Art Unit 1639